

Systematic Review Data Repository (SRDR) Training – Example Case for Blood Pressure Targets

Welcome to Systematic Review Data Repository (SRDR)!

In this module, we will ask you to initiate a new project, create an extraction form, and extract data from one study. The goal of this exercise is to familiarize new users with the SRDR by walking through the extraction of data from one sample study into a new systematic review project. Please plan to devote 2-2.5 hours for this part of the training.

All materials for successfully completing this training are provided, including step-by-step instructions and a sample study to extract. Please read the notes below before beginning these exercises.

Notes:

- Please use **Firefox, Google Chrome, IE 7, 8, 9 or Safari** browser when using SRDR
- Throughout this exercise, information specifically designated for entry into SRDR Web forms during this exercise will be noted in *italic blue*. Feel free to cut and paste these sections into the indicated fields.
- For more detailed information on how to use the SRDR site, please refer to the SRDR user manual which can be linked through the homepage.

Log In

1. Go to <http://srdr-dev.herokuapp.com/>.
2. Log in using your email address as your username and the password: *cochrane*
3. Once all logged in, go to the **My SRDR** tab located under the SRDR banner.
4. Locate the project entitled **Workshop extraction**.
5. Click **Add a Study**.

A. Extract Study Data

A-1. Key questions

1. On the **New Study** page, select the first option (**One study created individually**; see item **A** in Figure 1).
2. In the resulting **Add a Single Study** dialog appearing at the bottom of the page, select Key Questions 1 and 2 by marking the appropriate check boxes (see item **B** in Figure 1).
3. Click **Save and continue** (see item **C** in Figure 1).

Figure 1

SRDR SYSTEMATIC REVIEW DATA REPOSITORY

Home MySRDR Published Projects

Home My Projects New Study

Project: Blood Pressure Targets in CKD

New Study

Studies may be added to your project individually or in batches. Each study added must be associated with at least one extraction form. Extraction form managed from My Work or by clicking the button labeled "Create a New Data Extraction Form."

Please specify how you would like to add new studies to your project:

☒ One study created individually **A**

☐ Many studies, created with a list of PubMed IDs

Add a Single Study

Which key question(s) are addressed in this study?

☒ 1. What is the optimal blood pressure target for patients with CKD? **B**

☒ 2. What effect does proteinuria have on blood pressure in patients with CKD? **B**

Save And Continue **C**

A-2. Publication

1. Enter the following **PubMed ID** into the appropriate field :

15738453

2. Click **Retrieve** (see item **A** in Figure 2). The data fields below will be populated with information imported from PubMed.

Figure 2

Primary Publications

Although only a single publication may be marked as primary, users may denote multiple secondary publications as associated with each extracted study.

Enter a PubMed ID and press 'Retrieve' to automatically populate the primary publication form.

PubMed ID: **A**

Comments (0) | [PostView](#)

Trial Title:	<input type="text"/>
Publication Title:	The effect of a lower target blood pressure on the progression of kidney disease: long-term follow-up of the modification of diet in renal disease study.
Author(s):	Sarnak MJ., Greene T., Wang X., Beck G., Kusek JW., Collins AJ., Levey AS.
Affiliation:	Division of Nephrology, Tufts-New England Medical Center, Boston, Massachusetts 02111, USA.
Journal:	Annals of internal medicine
Year:	2005
Volume:	142
Issue:	5

Identifiers:

Add Publication Identifier

3. Please review the imported information and click **Save** when finished.
4. Click **Next** or move to the next tab.

A-3. Design details

1. On the **Design Details** page, fill in the following information (see highlighted area in Figure 3):

Q#	Question text:	Data to be entered:
1	Follow up	3 y (median 1.6y)
2	Inclusion criteria of the study	Kidney function: <i>CrCl<70 if proteinuria >3000mg/d; CrCl <45 if proteinuria 1000-3000 mg/d</i> BP: <i>ND</i>
3	Proteinuria exclusion criteria	<i>UPE <1000 mg/d if CrCl <45 mL/min per 1.73m2; UPE <3000 mg/d if CrCl is 45-70 mL/min/1.73m2</i>

2. Please review your responses and click **Save Data** when finished.
3. Click **Next** or move to the next tab.

Figure 3

The screenshot shows the 'Study Design Details' page of a web application. The page has a navigation bar with tabs: Key Questions, Publications, Design (selected), Arms, Arm Details, Baselines, Outcomes, Outcome Details, Results, Adverse Events, and Quality. The 'Study Design Details' section is highlighted with a red border. It contains four numbered sections:

- 1. Inclusion criteria for review**: A text input field containing 'RCTs and observational follow-up reports of RCTs comparing blood pressure'. Below it is a link 'Comments (0) | Post/View'.
- 2. Follow-up**: A text input field containing '3y (median 1.6y)'. Below it is a link 'Comments (0) | Post/View'.
- 3. Inclusion criteria of study**: Two dropdown menus. The first is labeled 'Kidney function (measured GFR or CrCl)' and contains 'CrCl<70 if prot'. The second is labeled 'BP' and contains 'ND'. Below the dropdowns is a link 'Clear Selections' and another link 'Comments (0) | Post/View'.
- 4. Proteinuria exclusion criteria**: A text input field containing 'UPE <1000 mg/d if CrCl <45 mL/min per 1.73m2; UPE <3000 mg/d if CrCl is 45-70'. Below it is a link 'Comments (0) | Post/View'.

At the bottom of the highlighted area is a green button labeled 'Save Data'.

A-4. Study Arms

1. Click **Add Arm** (see item **A** in Figure 4).

Figure 4

The screenshot shows the 'Editing Study' interface. On the left is a sidebar with navigation options like 'Project Information', 'Extraction Forms', and 'PROJECT STUDY DATA'. The main area has a top bar with 'Editing Study:' and study details. Below this is a tabbed interface with 'Arms' selected. The 'Study Arms' section contains the text 'There are no arms associated with this study. Please use the form below to add a new arm.' and a green 'Add Arm' button. A red box with a white 'A' and an arrow points to the 'Add Arm' button. At the bottom of the 'Study Arms' section are 'Previous' and 'Next' buttons.

2. In the resulting pop-up, choose **Low BP target** from the drop-down list (see item **A** in Figure 5).
- 5). In the arm description, enter **<130/80**
3. Click **Save** (see item **B** in Figure 5). The pop-up will close and the newly selected arm information will now appear in the arms table.

Figure 5

The screenshot shows the 'Add New Arm' pop-up form. It has a title bar 'Add New Arm' with a close button. The form contains the following fields:

- Arm Title:** A dropdown menu with 'Low BP target' selected. Below it is a red note: 'Arm titles found in the dropdown have been added to either the study extraction_form or are found in other studies within this same project. Use "Other..." to specify a new Arm title.'
- Arm Description:** A text input field containing '<130/80'. A red box with a white 'A' and an arrow points to this field.
- Participants Enrolled:** A text input field with a red note: 'Enter the number of participants initially enrolled for this arm of the study. You will have'.
- Is this an 'intention to treat' arm?:** A dropdown menu with 'Yes' selected.

At the bottom of the form are two buttons: a green 'Save' button and a grey 'Cancel' button. A red box with a white 'B' and an arrow points to the 'Save' button.

- Click the Add Arm button again. This time you will enter an additional arm by selecting **Other** from the dropdown menu.
- Specify the arm as *Usual BP target* and under arm description, enter *DBP <90*. (See Figure 6)
- Please review the arms information and click **Next** or move to the next tab when finished.

Figure 6

Add New Arm

Arm Title: Other

Please Specify:
Usual BP target

Arm titles found in the dropdown have been added to either the study extraction_form or are found in other studies within this same project. Use "Other..." to specify a new Arm title.

Arm Description: DBP<90

[Save](#) [Cancel](#)

- Both arms will appear in the list. (see Figure 7)

Figure 7

Study Arms

#	Arm Title	Arm Description	Actions
1	Low BP target		Edit Arm Delete Arm Comments (0) PostView
2	Usual BP target		Move Up Arm Edit Arm Delete Arm Comments (0) PostView

[Add Arm](#)

[Previous](#) [Next](#)

A-5. Arm Details

1. Enter in the following data (see Figure 8)

Arm	Target BP	Achieved BP
<i>Low BP Target</i>	<i><130/80</i>	<i>130/80</i>
<i>Usual BP Target</i>	<i>DBP<90</i>	<i>134/82</i>

Figure 8

Key Questions

Publications

Design

Arms

Arm Details

Baselines

Outcomes

Outcome Details

Results

Adverse Events

Quality

Arm Details

Enter your Arm Detail information for each arm using the entry fields below. Remember to **press the "Save" button** before exiting the page

1. BP measurements

Low BP target

Study

Target BP

Achieved BP

<130/80

130/80

Clear Selections

Usual BP target

Study

Target BP

Achieved BP

DBP<90

134/82

Clear Selections

Comments (0) | [Post/View](#)

Save Table Data

A-6. Baselines

1. Enter in the following data (see Figure 9):

Q#	Question text:	Data to be entered: Arm: Low BP target	Data to be entered: Arm: Usual BP target	Data to be entered: Arm: All Arms (Total)
1	Case of CKD	<i>leave blank</i>	<i>leave blank</i>	<i>ND (excluded T1DM)</i>
2	Race	<i>leave blank</i>	<i>leave blank</i>	<i>ND (conducted in Europe)</i>
3	Kidney function	<i>36</i>	<i>34</i>	<i>leave blank</i>
4	Proteinuria category	<i>leave blank</i>	<i>leave blank</i>	<i>100-5000 mg/d</i>
5	Proteinuria criteria	<i>Mean: UPE 2800 mg/d SD: 2000</i>	<i>Mean: UPE 2900 mg/d SD: 1900</i>	<i>leave blank</i>

2. Please review your responses and click **Save Table Data** when.

3. Click **Next** or move to the next tab.

Figure 9

Baseline Characteristics

Enter your baseline characteristic information for each arm using the entry fields below. Remember to **press the "Save" button** before exiting the page

1. Cause of CKD

Low BP target

Usual BP target

All Arms (Total)

 ND (excluded T1DM)

 Comments (0) | [Post/View](#)

2. Race

Low BP target

Usual BP target

All Arms (Total)

 ND (conducted in Europe)

 Comments (0) | [Post/View](#)

3. Kidney function

Low BP target

Usual BP target

All Arms (Total)

 measured GFR in mL/min/1.73m2
 Comments (0) | [Post/View](#)

4. Proteinuria category

<u>Low BP target</u>	<u>Usual BP target</u>	<u>All Arms (Total)</u>
<input type="radio"/> <300 mg/d	<input type="radio"/> <300 mg/d	<input type="radio"/> <300 mg/d
<input type="radio"/> 300-1000 mg/d	<input type="radio"/> 300-1000 mg/d	<input type="radio"/> 300-1000 mg/d
<input type="radio"/> 1000-5000 mg/d	<input type="radio"/> 1000-5000 mg/d	<input checked="" type="radio"/> 1000-5000 mg/d

[Clear Selections](#)

A-7. Outcome set up

1. On the **Outcome Setup** page, click **Add a New Outcome Name**.
2. In the resulting pop-up, select *Kidney failure* from the **Outcome Title** drop-down list. (See Figure 10)
3. In the **Outcome Description**, enter *ESRD*.
4. In response to **What type of outcome is this?**, select *Categorical* from the 3 options listed.
5. Enter *%* in the **Units** text box
6. In the textbox under **Define Outcome Timepoints** enter the following information

Numeric Value or Name	Time unit
3	years

7. Under **Define Patient Populations (Subgroups)**, click **Add A Subgroup**.
8. In the text box under **Name**, enter *Patients with baseline proteinuria $\geq 3\text{g}/24\text{h}$* .
9. Again, click **Add A Subgroup** and enter *Patients with baseline proteinuria 1-3g/24h*.
10. Click **Save**.

Figure 10

Add New Outcome

Basic Setup

Outcome Title: Kidney failure
Outcome titles in the menu above have either been added to the extraction form or are found in other studies within this project. Use "Other..." to specify a new outcome title.

Outcome Description: ESRD

What type of outcome is this?
☒ Categorical
☐ Continuous
☐ Time to Event

Units: %

Notes:

Define Outcome Timepoints

<u>Numeric Value or Name</u>	<u>Time Unit</u>
Median 1.6	years

[Add A Timepoint](#)

Define Patient Populations (Subgroups)

<u>Name</u>	<u>Description</u>
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Save **Cancel**

11. Repeat steps 21-30 for the following outcome:

Outcome Title	<i>Mortality</i>
Outcome Description	<i>Leave blank</i>
What type of outcome is this?	<i>Categorical</i>
Units	<i>%</i>
Define outcome timepoints	<i>3 years</i>
Subgroups	<i>None (skip this step)</i>

12. Please review your entries and click **Next** or move to the next tab when finished.

A-8. Outcome Details

1. In this section, enter *ESRD* as the primary outcome.
2. Click **Next**

A-9.Outcome Results

In this section, you will be creating analysis tables based on the information that you have previously entered.

1. From the drop-down list labeled **Step 1. Choose the outcome and population to enter data for**, select:
Kidney failure (from 1st drop-down) (see item **A** in Figure 11).
And
All Participants (from the 2nd drop-down) (see item **B** in Figure 11)
2. Within the table, click **Edit Measures** (see item **C** in Figure 11).
 - a. Unselect **N Enrolled**, **Counts**, and **Standard Deviation**
 - b. Select **N Analyzed** and **Percentage**
 - c. Click **Save**
3. Enter the following values into the table under the appropriate arms:

	<i>Arm: Low BP target</i>	<i>Arm: Usual BP target</i>
N Analyzed	<i>167</i>	<i>168</i>
Percentage	<i>23</i>	<i>20</i>
Counts	<i>38</i>	<i>34</i>

4. Click **Save Table Data**. (see item **D** in Figure 11)
5. Click on the blue box labeled **Create Between-Arm Comparisons**.
6. Within the table, click **Edit Measures**. (see item **E** in Figure 11)
 - a. Unselect **Statistical test**, **Odds Ratio (OR)**, and **Standard Deviation**
 - b. Select **P-Value**
 - c. Click **Save**
7. From the drop-down box select, *Low BP target* vs. *Usual BP target*.
8. Enter *0.99*
9. Click **Save Table Data**. (see item **D** in Figure 11)

Figure 11

Key Questions Publications Design Arms Arm Details Baselines Outcomes Outcome Details Results Adverse Events Quality

Step 1. Choose the outcome and population to enter data for: Kidney failure **A** All Participants **B** Comments (0) | [Post/View](#)
OR [View/Modify Existing Data Entries](#)

Note: After successfully saving data to the table, you may double-click on the cell containing data to set footnotes and other options.

Outcome: Kidney failure (%) Description: Population: All Participants					
Descriptive Statistics				Between-Arm Comparisons	
Time Point	Measure	Low BP target	Usual BP target	Measure	Low BP target vs Usual BP target
3 years Remove	Percentage	23	20	P-Value	0.99
	N Analyzed	167	168		
	Counts	38	34		
Edit Measures C				Edit Measures E	
				Add Column Remove Comparisons	
Save Table Data D					

10. Now choose the subgroup for *Patients with baseline proteinuria $\geq 3\text{g}/24\text{h}$* from the 2nd drop-down under **Step 1**.

11. Enter the following data (see Figure 12):

	Arm: Low BP target	Arm: Usual BP target
N Analyzed	58	62
Percentage	nd	nd
Between Arm Comparison	<i>Low BP Target vs. Usual BP Target</i>	
P-Value	0.81	

Figure 12

Key Questions Publications Design Arms Arm Details Baselines Outcomes Outcome Details Results Adverse Events Quality

Step 1. Choose the outcome and population to enter data for: Kidney failure UPE ≥ 3000 mg/d Comments (0) | [Post/View](#)
OR [View/Modify Existing Data Entries](#)

Note: After successfully saving data to the table, you may double-click on the cell containing data to set footnotes and other options.

Outcome: Kidney failure (%) Description: Population: UPE ≥ 3000 mg/d					
Descriptive Statistics				Between-Arm Comparisons	
Time Point	Measure	Low BP target	Usual BP target	Measure	Low BP target vs Usual BP target
3 years Remove	Percentage	nd	nd	P-Value	0.81
	N Analyzed	58	62		
Edit Measures				Edit Measures	
				Add Column Remove Comparisons	
Save Table Data					

12. Repeat for subgroup *Patients with baseline proteinuria 1-3g/24h* the following outcomes:

	Arm: Low BP target	Arm: Usual BP target
N Analyzed	109	106
Percentage	nd	nd
Between Arm Comparison	<i>Low BP Target vs. Usual BP Target</i>	
P-Value	0.89	

13. Repeat steps 1-9 for the **Mortality** outcome entering the following data:

Outcome Mortality		
	Arm: Low BP target	Arm: Usual BP target
N Analyzed	167	168
Percentage	2	1
Between-Arm comparison	<i>NONE (no need to enter data)</i>	

A-10. Adverse Events

1. Click **Add New Row**.
2. In the table that appears enter the following data (see Figure 13):

Title	<i>Treatment-related adverse events</i>	
Description	<i>Leave blank</i>	
	Low BP target	Usual BP target
Percent	<i>4%</i>	<i>2%</i>
P-value	<i>leave blank</i>	<i>leave blank</i>
Title	<i>SAEs</i>	
Description	<i>Leave blank</i>	
	Low BP target	Usual BP target
Percent	<i>23%</i>	<i>17%</i>
P-Value	<i>Leave blank</i>	<i>Leave blank</i>

3. 46. Click **Save Table Data**.

Figure 13

The screenshot shows a web application interface for managing Adverse Events. At the top, there is a navigation bar with tabs: Key Questions, Publications, Design, Arms, Arm Details, Baselines, Outcomes, Outcome Details, Results, Adverse Events (selected), and Quality. Below the navigation bar, the 'Adverse Events' section is displayed. It features a table with the following structure:

Arm or Total	Title	Description	Percent	P-value	Actions
Low BP target	Treatment-related AEs		4%		Delete Adverse Event Comments (0) Post/View
Usual BP target			2%		
Low BP target	SAEs		23%		Delete Adverse Event Comments (0) Post/View
Usual BP target			17%		

Below the table, there are two buttons: a green 'Save Table Data' button and a grey 'Add New Row' button.

A-11. Quality

1. Select the following **Values** from the drop-down menus for each of the questions listed (see Figure 14):

1	What is the risk of selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence?	<i>Low</i>
2	What is the risk of selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment?	<i>Low</i>
3	For each main outcome or class of outcomes, what is the risk of performance bias due to knowledge of the allocated interventions by participants and personnel during the study (lack of study participant and personnel blinding)?	<i>Low</i>
4	Was the care provider blinded to the intervention?	<i>Other</i> , Please specify: <i>Yes</i>
5	For each main outcome or class of outcomes, what is the risk of detection bias due to knowledge of the allocated interventions by outcome assessment (lack of outcome assessor blinding)?	<i>Low</i>
6	For each main outcome or class of outcomes, what is the risk of attrition bias due to amount, nature, or handling of incomplete outcome data?	<i>Low</i>
7	What is the risk of reporting bias due to selective outcome reporting?	<i>Low</i>
8	Are there other biases due to problems not covered in 1-6?	<i>No</i>
9	Were all randomized participants analyzed in the group to which they were allocated?	<i>Yes</i>
10	Were the groups similar at baseline regarding the most important prognostic indicators?	<i>Yes</i>
11	Were co-interventions avoided or similar?	<i>Yes</i>
12	Was the compliance acceptable in all groups?	<i>Yes</i>
13	Was the timing of the outcome assessment similar in all groups?	<i>Yes</i>
14	Are there other risks of bias? If yes, describe them in the Notes.	<i>No</i>

2. Please review your entries and click **Save Table Data** when finished.

Figure 14

Study List >>

Complete List (4 Total)

Author Undefined (No PMID)

Wright JT Jr (12435255)

Peterson JC. (7574193)

Ruggenenti P (15766995) >>

Add New Study

PROJECT TOOLS

View Summary

Publish Externally

Data Comparison Tool

Data Export Tool *

File Repository *

Graphical Data View & Stats *

Report Builder

HELP INFORMATION

User Manual and FAQ

Feedback

Note: * = Coming Soon

Key Questions

Publications

Design

Arms

Arm Details

Baselines

Outcomes

Outcome Details

Results

Adverse Events

Quality

Enter Quality Dimensions

Dimension	Value	Notes	Instructions	Actions
What is the risk of selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence? [Low, Unclear, High]	Low		A random (unpredictable) assignment sequence. Examples of adequate meth...	Comments (0) Post/View
What is the risk of selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment? [Low, Unclear, High]	Low		Adequate allocation concealment involves assignment generated by an ind...	Comments (0) Post/View
For each main outcome or class of outcomes, what is the risk of performance bias due to knowledge of the allocated interventions by participants and personnel during the study (lack of study participant and personnel blinding)? [Low, Unclear, High]	Low		Adequate participant blinding occurs if the index and control groups ar...	Comments (0) Post/View
Was the care provider blinded to the intervention? [Low, Unclear, High]	Other... Please Specify: Yes		Adequate personnel blinding occurs if the index and control groups are ...	Comments (0) Post/View
For each main outcome or class of outcomes, what is the risk of detection bias due to knowledge of the allocated interventions by outcome assessment (lack of outcome assessor blinding)? [Low, Unclear, High]	Low		Adequate outcome assessor blinding occurs if: a) for patient-reported o...	Comments (0) Post/View
For each main outcome or class of outcomes, what is the risk of attrition bias due to amount, nature, or handling of incomplete outcome data? [Low, Unclear, High]	Low		The number of participants who were included in the study but did not c...	Comments (0) Post/View
What is the risk of reporting bias due to selective outcome reporting? [Low, Unclear, High]	Low		In order to have low risk of selective outcome reporting bias, the revl...	Comments (0) Post/View
Are there other biases due to problems not covered in 1-6? [Yes, No]	No		These may include the following.	Comments (0) Post/View
Were all randomized participants analyzed in the group to which they were allocated? [Yes, No, Unsure]	Yes		All randomized patients are reported/analyzed in the group they were al...	Comments (0) Post/View
Were the groups similar at baseline regarding the most important prognostic indicators? [Yes, No, Unsure]	Yes		In order to receive a 'yes', groups have to be similar at baseline rega...	Comments (0) Post/View
Were co-interventions avoided or similar? [Yes, No, Unsure]	Yes		This item should be scored 'yes' if there were no co-interventions or L...	Comments (0) Post/View
			The reviewer determines if the	

3. Scroll to the bottom of the screen and enter **EPC** in the **Quality Guideline Used** field (see item **A** in Figure 15).
4. Choose **Good** from the drop-down list labeled **Select Current Overall Rating** (see item **B** in Figure 15).
5. Click **Save Quality Rating** when finished.

Figure 15

Adjust Quality Rating

Quality Guideline Used: EPC ← **A**

Select Current Overall Rating: Good ↓ ← **B**

Notes on this Rating:

Save Quality Rating

Previous

6. Click **Save Quality Rating**.

*You have completed the **Extract Study Data** exercise*